UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/791,635 | 03/02/2004 | Joseph Rock | US010382A | 3051 |

28159 7590 02/01/2007

PHILIPS MEDICAL SYSTEMS
PHILIPS INTELLECTUAL PROPERTY & STANDARDS
P.O. BOX 3003
22100 BOTHELL EVERETT HIGHWAY
BOTHELL, WA 98041-3003

| EXAMINER | |
|---|---|
| PATEL, NATASHA | |
| ART UNIT | PAPER NUMBER |
| 3766 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/01/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/791,635 | ROCK ET AL | |
| | Examiner | Art Unit | |
| | Natasha N. Patel | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6,9-14 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No: _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The Amendment filed on 14 November 2006 has been received and considered. By this amendment, Claims 1-3, 5-6, 9-14, and 16 have been amended, Claims 7-8, 15, and 17-25 have been cancelled, and Claims 1-6, 9-14, and 16 are now pending in the application.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 9, 11-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilof et al. (US Patent 5,191,885) in view of Perlin (US Patent 4,476,872).

3. Regarding Claim 1, Bilof discloses a system providing cardiac stimulation in combination with an endoscopic imaging probe (see col. 1, lines 50-51), comprising: a cardiac stimulation electrical conductor (see conducting member 36a; col. 3, lines 39-40); and an electrical cable (see cable 44; col. 3, lines 54-56), attached to the cardiac stimulation electrical conductor (see Figure 6), and adapted to be connected to an external defibrillator (see external defibrillator 50 or 102; col. 3, lines 56-66 and col. 6, lines 22-29). Bilof discloses a disposable, removable protective sheet affixed to the endoscopic imaging probe (see sheet member 76; col. 5, lines 33-44), wherein the cardiac stimulation electrical conductor (see conductor 66a or 36a) are integrated with

the protective sheet (see Figure 8). Furthermore, since protective sheet 76 only extends up to plastic extension member 40, cable 44 is not protected by the sheet (see Figure 6). However, Bilof does not disclose that the protective sheet forms a sheath, which by definition requires some type of enveloping structure or enclosing cover. Nevertheless, sheaths are well known in the medical lead art. For example, Perlin discloses a disposable, removable sheath (see housing 12; col. 2, lines 4-7). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a sheath that covers Bilof's entire probe and not just the conductors because Perlin teaches that sheaths are useful in lowering the cost of probe production and increasing the convenience of probe sterilization (see col. 1, lines 13-51).

4. Regarding Claim 2, Bilof discloses a connector receiving the cable and adapted to connect the cable to the external defibrillator (see switch 46; col. 3, lines 56-63 and Figure 6); and a transthoracic pad connected to the external defibrillator for the cardiac stimulation (see col. 6, lines 28-35; Figure 11).

5. Regarding Claim 3, Bilof discloses a second cardiac stimulation electrical conductor (see conducting member 36b or 66b) located on the sheath, wherein an electrical path for cardiac stimulation is provided between the first and second conductors (see electrical connector 40; col. 3, lines 46-54).

6. Regarding Claim 9, Bilof discloses at least one of the first and second conductors comprises a plurality of electrically connected conductors (see conducting members 36c-36f; col. 3, lines 40-50).

7. Regarding Claim 11, Bilof discloses that the endoscopic imaging probe further comprises a transesophageal ultrasound probe (see col. 4, lines 3-5 and 60-64).

8. Regarding Claims 12 and 13, Bilof discloses that the cardiac stimulation comprises cardioversion, defibrillation or pacing in the atria and the ventricles of a subject (see col. 4, lines 37-39). The examiner considers that the heart H includes both atria and ventricles.

9. Regarding Claim 14, Bilof discloses that the cardiac stimulation comprises cardioversion, defibrillation or pacing of any of a plurality of pacemaker sites within a heart of a subject (see col. 3, lines 62-66 and col. 4, lines 53-59). The examiner considers that since the probe has multiple electrodes (see electrodes 22-32), a pair of electrodes is selected to carry out stimulation, and the electrodes are spaced apart from one another, then a plurality of sites must necessarily be stimulated.

10. Regarding Claim 16, Bilof discloses that the transthoracic pad is positioned over a thorax of a subject (see Figure 11).

11. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilof et al. (US Patent 5,191,885) and Perlin (US Patent 4,476,872) in view of Crowley (US Patent 5,588,432).

12. Regarding Claim 4, Perlin discloses that the sheath is made of plastic (see col. 2, lines 16-17). However, Perlin does not disclose that the sheath is a flexible plastic. Crowley discloses a similar disposable sheath made of flexible membrane material (see col. 12, lines 47-49). It would have been obvious to one of ordinary skill in the art at the

time of the invention to make the sheath flexible because Crowley teaches that it permits more movement of the probe (see col. 12, lines 50-53).

13. Regarding Claim 10, neither Bilof nor Perlin disclose an acoustically transparent conductor. Crowley teaches catheter construction using acoustically transparent conductors for the purpose of enabling sensing and stimulation of tissue while not obstructing the monitoring of the tissues acoustically. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acoustically transparent conductors in the modified Bilof system in order to avoid compromised acoustically monitoring results that fail to disclose the impact of the acoustical testing on all the tissue in the test site (see col. 14, lines 31-36).

14. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilof et al. (US Patent 5,191,885) and Perlin (US Patent 4,476,872) in view of Pless et al. (US Patent 4,640,298).

15. Regarding Claim 5, Bilof discloses that the probe is insertable through a mouth into an esophagus of a patient (see col. 4, lines 24-25). Bilof also discloses an insulation type coating (see col. 5, lines 34-38) to protect the probe from damage (see col. 5, lines 36-38). Modified Bilof does not disclose that this insulative coating is on the sheath. Pless discloses an insulating sheath (see col. 5, lines 43-45 and Figure 2). Since the purpose of insulation is to separate the conductor (leads 7) from conducting bodies (electrode material 5) by means of nonconductors (insulating sheath 3) so as to prevent transfer of electricity, heat, or sound (Merriam-Webster's Medical Dictionary, © 2002 Merriam-Webster, Inc), insulative sheath 3 inherently has a suitable dielectric

strength to protect the probe from damage during stimulation. Otherwise, the insulative sheaths would not be insulative.

16. Regarding Claim 6, Bilof does not disclose an inflatable balloon. However, Pless discloses a similar esophageal probe that has an insulating sheath (see sheath 3; col. 5, line 43) further comprising an inflatable balloon (see either balloon 4Y or 4Z) positioned behind the conductor (see electrode material 5 in Figure 2) closing a gap between the esophagus and the sheath and pushing the conductor against a wall of the esophagus (see col. 4, lines 59-63). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Pless's inflatable balloon configuration in order to achieve the desired close contact between electrodes and the heart, thereby reducing current intensity and potential differences as taught by Pless (see col. 3, lines 12-16).

***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wang et al. (US Patent 6,980,865).

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
1/24/07

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766